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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/621,620

07/17/2003

Graham M. Clarke

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EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

01/14/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com  
LegalDocketing@mmm.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/621,620	<b>Applicant(s)</b> CLARKE ET AL.	
	<b>Examiner</b> CATHERINE N. WITCZAK	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-8 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherman et al (US 2002/0020688).

Sherman et al disclose in Figure 11 a microneedle device which is used to contact the skin (paragraph [0009]) comprising a substrate (140), a plurality of microneedles (182, 184) formed of polymers (paragraphs [0015] and [0016]) comprising a base that is tapered to a flat truncated tip distal the base. Sherman et al further disclose in paragraphs [0067], [00638], [0075] and [0076] the dimensions for A11/12/13/14 being between 0 and 45 degrees; the width of the micropillars 122/124 (and thus the microneedle bore) being between 1 and 49 microns; and the

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height L12 of the microneedle being between 50 and 200 microns. The microneedle Sherman et al disclose is formed using a mold process in which a film (130) is pressed between mold 110 and micropillars 122/124 (see Figures 7-11). Using the dimensions given for the mold components, one possible resulting microneedle formed using this process would have an angle A11/12/13/14 of 9.32 degrees, an inner bore with an inner diameter of 49 microns, a maximum base dimension (i.e. the diameter of the base of the microneedle) which is 66.66 microns - providing for a base area of at least 900 square microns; and a height of 200 microns which is 3 times that of the base. Furthermore, as there must be some degree of clearance between the micropillar and the top mold 110 (so that the micropillar covered by the film can be fully pressed into the mold during the steps shown in Figures 9 and 10), the tip of the microneedle will have a flat rim having some degree of thickness. A clearance of even 0.13 microns between the outer wall of the micropillar and the top mold 110 would provide for the top surface of the microneedle having an area of at least 20 square microns.

### ***Response to Arguments***

Applicant's arguments filed 9/11/09 have been fully considered but they are not persuasive. Applicant argues that Sherman does not disclose a microneedle having a tip surface area of at least 20 square microns. Examiner disagrees. The method of manufacturing the microneedle as taught by Sherman et al in Figures 7-11 involves pressing a film 130 between a mold 110 and a solid micropillar. In order for the molding process to be successful, the micropillar must be able to be fully pressed into the mold. Thus, as mentioned above, some clearance must exist between the outer surface of the micropillar and the mold – otherwise, if the dimensions were exactly equal, it would not be possible to fully insert the micropillar into the mold. Adding to this, not only must the clearance be sufficient to allow for the micropillar to fit within the mold, but the thickness of the film must also be taken into consideration in adjusting

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the diameter of the mold. For example, in a situation in which the angle A11/12 were chosen to be 0 (so as to form a tubular microneedle) if one were to make the inner diameter of the mold 110 equal exactly to the outer diameter D11 of the micropillar, the two mold components would simply abut each other when brought together. Once the diameter of the mold were sufficiently increased, the resulting cylindrical microneedle would have a rim width equal to this difference in diameters. As set forth in the rejection above, a clearance of even 0.13 microns would be sufficient for the resulting microneedle tip surface to meet the claimed requirement of the tip surface area being at least 20 square microns.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Catherine N Witzak/

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